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November 29, 2018

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Hon. Paul W. Grimm
United States District Judge
District of Maryland
6500 Cherrywood Lane
Greenbelt, MD 20770

Re: *American Academy of Pediatrics v. Food and Drug Administration*, No. 8:18-cv-883-PWG

Dear Judge Grimm:

Pursuant to the Court's November 27, 2018 Order, Plaintiffs file this response to FDA's Notice (Dkt. 51) of Commissioner Gottlieb's recent statement announcing a proposed "policy framework" intended to address the "astonishing increases in kids' use of e-cigarettes." Gottlieb Statement 2, 3 (Dkt. 51-1). Plaintiffs welcome FDA's attention to the public health crisis of e-cigarette use—an epidemic that has occurred, at least in significant part, due to FDA's unlawful and unreasonable decision in the 2017 Guidance to suspend for nearly a half decade or more statutory premarket review requirements for thousands of addictive tobacco products. Plaintiffs also welcome FDA's recognition of the need for regulatory intervention to stem this crisis.

The Commissioner's statement, however, neither undermines Plaintiffs' claims in this case nor eliminates the need for prompt relief from FDA's illegal action. To start, FDA has not actually taken *any* formal agency action to implement the proposed framework. It has neither revised the Guidance nor indicated when or how it might do so. It has simply announced its "intent" to "[r]evisit" the Guidance. Notice 1-2; Gottlieb Statement 4-5. An "intent" to take an undefined action at an undefined time does not alter the fact that the Guidance remains fully in effect. Indeed, the Commissioner's statement makes clear that even FDA recognizes that its failure to enforce the Tobacco Control Act as written may well be contributing to the rise in youth e-cigarette use, demonstrating the urgent need to compel FDA to carry out its statutory responsibilities.

More fundamentally, even were FDA to implement proposed revisions to the Guidance consistent with the Commissioner's statement, those revisions would not materially affect, much less defeat, either the justiciability or substance of Plaintiffs' claims. Tellingly, FDA does not claim in its Notice that proposed revisions to the Guidance, if implemented, would render Plaintiffs' claims moot. Nor could FDA reasonably take that position. That is because the Guidance, even as FDA suggests it plans to revise it, would contain the same legal defects as the August 2017 Guidance.

From a legal perspective, the fundamental problem with FDA's proposed revisions is that those modifications would stop well short of faithfully administering the statutory scheme as

Congress designed it. In the Tobacco Control Act, Congress established a comprehensive regime for the regulation of tobacco products, requiring review by FDA of *all* new tobacco products *before* they are marketed to the public, subject only to exemptions that Congress itself created. *See, e.g.*, Pls.' MSJ Reply 17-21 (Dkt. 39). Yet the Commissioner's proposed revisions to the Guidance—relying on a sweeping concept of "enforcement discretion"—would perpetuate a multi-year exemption from premarket review for certain classes of e-cigarettes (those with certain flavors regardless of where they are sold and those with other flavors depending on where or how they are sold), allowing them to remain on the market absent the public health review Congress mandated. The proposed revisions would also perpetuate a multi-year exemption from premarket review for unflavored cigars, similarly allowing them to remain on the market without undergoing required review. By shuttering the premarket review of thousands of potentially dangerous and addictive tobacco products and by permitting those products to remain on the market for years without the public health review required by Congress, the Guidance, as revised, would remain "ultra vires" agency action. *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013).[1]

In addition, the proposed revisions to the Guidance strongly support Plaintiffs' position that the Guidance—far from simply not enforcing statutory requirements—affirmatively invites and authorizes manufacturers to market and sell tobacco products in violation of federal law. *See* Pls.' MSJ Mem. 14-15 (Dkt. 31-2); Pls.' MSJ Reply 20-22, 29-30; *Utility Air Regulatory Group v. EPA*, 134 S. Ct. 2427, 2445-2446 (2014). According to the statement, the Commissioner is not asking FDA to revisit the Guidance with respect to "mint- and menthol-flavored" e-cigarettes because, in the Commissioner's view, "the *availability* of these flavors … may be important to adult smokers." Gottlieb Statement 4 (emphasis added). That is additional evidence of what has always been clear: FDA expects *and* intends that tobacco products exempted from premarket review under the Guidance will continue to be marketed and "availab[le]" despite Congress's prohibition on the marketing of such products. *See* 21 U.S.C. § 387j(a)(2), (c)(1)(A)(i). Rather than administer the Tobacco Control Act's premarket review regime as Congress designed it, the proposed revisions to the Guidance would continue to substitute the *agency's* exercise of its

[1] FDA is therefore wrong in asserting in the Notice (at 2) that the Commissioner's statement proves that there has been no abdication by FDA of its statutory responsibilities. Setting aside that the Guidance has yet to be changed, the revised Guidance would continue multi-year, categorical exemptions for e-cigarettes and cigars based on general criteria such as flavor or method of distribution. That would remain a "conscious[] and express[] … general policy" that amounts to abdication. *Heckler v. Chaney*, 470 U.S. 821, 833 n.4 (1985). Moreover, the abdication issue is relevant only as a response to FDA's (untenable) position that *Chaney* forecloses judicial review of the Guidance; even if the revised Guidance did not amount to statutory abdication, it would still be ultra vires—as it would remain contrary to the text, structure, and purposes of the Tobacco Control Act, as Plaintiffs have explained—and FDA's *Chaney* argument fails for reasons independent of abdication, again as Plaintiffs have already explained. *See, e.g.*, Pls.' MSJ Reply 23-25, 27-30.

purported unlimited "enforcement discretion" for *Congress's* judgments as to when and how premarket review should be required and for which products. The proposed revisions thus underscore both why the Guidance is ultra vires and why the Guidance does far more than defer enforcement of FDA's statutory duties.

In sum, even were FDA to revise the Guidance in accordance with the November 15 announcement, all of Plaintiffs' claims would remain justiciable, and all would continue to require vacatur of the Guidance. The Guidance, as revised, would remain ultra vires agency action (Count I of Plaintiffs' complaint). It would remain unlawful because it was adopted in August 2017 without complying with the APA's notice-and-comment requirements (Count II of Plaintiffs' complaint). And it would remain arbitrary and capricious because it was adopted in defiance of basic requirements of reasoned decision-making (Count III of Plaintiffs' complaint).

Nor does the Commissioner's statement demonstrate that the Guidance is not "final agency action," as FDA claims. Notice 2. The Guidance today remains in effect, exempting nearly 25,000 products from premarket review. FDA's intent to "[r]evisit" the Guidance, *id.*—not to abandon it wholesale, but to consider modifying it to require premarket review of some flavored products or products sold through specific channels—in no way suggests that the Guidance is anything other than final. The Guidance has governed and continues to govern FDA's application of the Tobacco Control Act. Indeed, it is precisely because the Guidance has legally and practically binding effects on the agency and industry that FDA *must* revisit and modify it in order to implement the Commissioner's proposed policy framework. That FDA at some point may in fact modify the Guidance—a possibility true of any agency decision—does not render the Guidance non-final. *See* Pls.' MSJ Reply 14-17.

For those reasons and others, Plaintiffs respectfully submit that timely judicial review of the Guidance remains decisively in the public interest—a point confirmed by FDA's belated recognition of the public health epidemic the Guidance has fueled. As Plaintiffs have previously explained, they stand ready to participate in oral argument at this Court's earliest convenience if the Court determines such argument would be useful in resolving Plaintiffs' claims.

Respectfully submitted,

/s/
Kelly P. Dunbar

cc: Eric Beckenhauer, Esq. (by CM/ECF)